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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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02/426,509 04/21/95 DILLRICH

11/12/96

EXAMINER

1842/0211

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1155 AVENUE OF THE AMERICAS
NEW YORK NY 10036-2711

ART UNIT

PAPER NUMBER

16

DATE MAILED: 02/11/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☒ Responsive to communication filed on 11/12/96 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-692. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-13, 23-30, 31-55 are pending in the application.
Of the above, claims 1-13, 23-30 are withdrawn from consideration.
2. ☒ Claims 14-22 have been cancelled.
3. ☒ Claims 31, 34, 40, 41, 48, 49, 55 are allowed.
4. ☒ Claims 32, 33, 35, 36, 38, 39, 42-44, 46, 47, 50, 54 are rejected.
5. ☒ Claims 37, 45 are objected to.
6. ☒ Claims 1-13, 23-30, 31-55 are subject to restriction or election requirement.
7. ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☒ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

1. Claims 1-13 and 23-55 are pending in the instant application.

Claims 1-13 and 23-30 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 10.

Claims 31-55 are examined in the instant application.

2. The objection to claims 15, 17, and 19 as not complying with § 1.821(d) is withdrawn.

The rejection of claims 14, 16, 18, and 20-22 under § 112, first paragraph, is withdrawn.

The declarations filed on November 12, 1997, under 37 CFR 1.131 are sufficient to overcome the Bennett. et al and Lee et al. references. The rejection of claims 14 and 15 under § 102(a) as being anticipated by Bennett et al. is withdrawn. The rejection of claims 18 and 19 under § 103 as being unpatentable over Lee et al. in view of Sambrook et al. is withdrawn.

The rejection of claims 18 and 19 under § 103 as being unpatentable over Cance et al. (1993) in view of Sambrook et al. is withdrawn.

The rejection of claim 20 under § 103 as being unpatentable over Bennett et al. in view of Maniatis et al.

The rejection of claim 22 under § 103 as being unpatentable over Lee et al. or Cance et al. (1993) in view of Maniatis et al. is withdrawn.

3. The amendment to the specification on page 2 of the response has not been entered because the line numbers are incorrect.

The amino acid sequence disclosed in figure 6 is not the same as that shown in SEQ ID NO: 6. The amino acid sequence set forth in the figure is not continuous, while SEQ ID NO: 6 is one continuous sequence.

In figures 1-3, the signal sequence is not marked the way as suggested by the Brief Description of the Drawings.

4. Claims 37 and 45 are objected to as not complying with §1.821(d) of the Sequence Rules and Regulations. When the description or claims of a patent application discuss a sequence listing that is set forth in the "Sequence Listing" in accordance with paragraph © of the Sequence Rules and Regulation, reference must be made to the sequence by use of the assigned identifier, in the text of the description and claims of the patent application. Claims 37 and 45 do not refer to sequences by their sequence identifiers. If the disclosed sequences are within SEQ ID NO: 2 and 4, it is suggested that the claims be amended by referring to them as amino acids # to # of SEQ ID NO: 2 or 4. Page 40 should be amended in a similar manner. It is suggested that applicant revise the application carefully to make sure that all disclosed sequences are referred to by their sequence identifiers.

5. Claims 38, 39, 46, 47, 53, and 54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 38, 39, 46, 47, 53, and 54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to MKK variants lacking structural domains residing in the internal region of the protein. The specification discloses the full length MKK but does not disclose variant MKK proteins lacking internal structural domains such as the SH2, SH3, tyrosine kinase, or the pleckstrin domain. Deletion of any one of these domains results in a polypeptide that is structurally distinct from MKK1 (SEQ ID NO: 2), MKK2 (SEQ ID NO: 4), or MKK3 (SEQ ID 6) because residues that are at certain distances from each other, now lie closer together. The conformation of the variant is not the same as the native MKK; therefore, the variant is functionally distinct from the native MKK. It is acknowledged that the specification provides general guidance for obtaining truncated MKK polypeptides lacking the carboxyl terminus containing the tyrosine kinase domain. However, such a variant is not representative of all the claimed variants. Deletion of the first few residues from the amino terminus or the last few residues from the carboxyl terminus does not affect the rest of the protein and therefore, is not the same as removing portions from the middle of the protein and connecting the rest. As mentioned earlier, removing internal portions of the polypeptide changes the conformation and affects the functional activity of the protein. It is not predictable that a MKK variant lacking an internal portion can be used to generate antibodies specific for the MKK polypeptide. Thus, the specification does not describe or support the claimed variants and does not enable the skilled

artisan to make and/or use the claimed variants.

6. Claims 32, 33, 35, 36, 38, 39, 42, 43, 44, 46, 47, and 50-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear as to what are the alternative embodiments of claims 32, 33, 38, 39, 42, 43, 46, 47, 50, 51, 53, and 54. The claims fail to recite proper Markush language (see MPEP § 2173.05(h)). It is suggested that the claims be amended in the following manner, "An isolated protein containing a peptide domain selected from the group consisting of SH2, SH3..." or "An isolated protein of claim # containing an amino acid sequence selected from the group consisting of amino acids 122 to 196 of SEQ ID NO: 2...." It is pointed out that the specification does not use the term Src homology 2 (or 3) peptide domain for SH2 (or SH3). For consistency with the specification, it is suggested that SH2 and SH3 be used in the claims.

Claims 35, 36, 44, and 52 are vague and indefinite. It is no longer clear as to what is fused to a heterologous peptide. Is it the recited peptide or the isolated protein comprising the peptide? Is the claim drawn to a fusion protein comprising the isolated protein of the previous claims fused to another protein? If the claimed invention is directed to a fusion protein, then the claims should be amended accordingly. It is suggested that the term "heterologous" be replaced with a term that clarifies the claimed invention because it is not clear as to what is encompassed by "heterologous peptide". Is it a peptide from another specie or another tyrosine kinase?

7. Claims 39, 43, 47, 51, and 54 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 39 is an improper dependent claim because according to figure 1 the SH3 domain contains 49-111. Claim 38 lacks amino acids 49-111, while its dependent claim, claim 39, is broader and lacks amino acid 48-111.

Claims 43, 47, 51, and 54 do not further limit the subject matter of a previous claim. For example, amino acids 25 to 169 of SEQ ID NO: 4 make up the pleckstrin domain of SEQ ID NO: 4 (claim 42). These claims seem to be identical in scope with the claim from which it depends.

Claims 32 and 33 are proper dependent claims because the SH3 domain of claim 32 is amino acids 49-111 of SEQ ID NO: 2, and a protein containing amino acids 48-111 comprises the SH3 domain of MKK1 having SEQ ID NO: 2. They are not identical in scope.

8. Claims 31, 34, 40, 41, 48, 49, and 55 are allowable.

Claims 37 and 45 are objected to for not complying with sequence rules.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire **THREE MONTHS** from the date of this action. In the event a first response is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to Sally Teng, Ph.D., at telephone number (703)308-4230. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, S. Walsh, can be reached at telephone number (703)308-2957.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-0196.

Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703)308-0294.

Sally P. Teng *SP*
February 7, 1997

Stephen Walsh
STEPHEN WALSH
SUPERVISORY PATENT EXAMINER
GROUP 1800